Complete Summary

GUIDELINE TITLE

ACR Appropriateness Criteria® sudden onset of cold, painful leg.

BIBLIOGRAPHIC SOURCE(S)

Mettmann MA, Brozzetti KA, Yucel EK, Holtzman SR, Baum RA, Foley WD, Ho VB, Mammen L, Narra VR, Rybicki FJ, Stein B, Moneta GL, Expert Panel on Vascular Imaging. ACR Appropriateness Criteria® sudden onset of cold, painful leg. [online publication]. Reston (VA): American College of Radiology (ACR); 2008. 5 p. [24 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Bettmann MA, Levin DC, Gomes AS, Grollman J, Henkin RE, Hessel SJ, Higgins CB, Kelley MJ, Needleman L, Polak JF, Stanford W, Wexler L, Abbott W, Port S. Sudden onset of cold, painful leg. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):101-5.

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Sudden onset of cold, painful leg

GUIDELINE CATEGORY

Diagnosis
Evaluation

CLINICAL SPECIALTY

Emergency Medicine
Family Practice
Internal Medicine
Nephrology
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of initial radiologic examinations for sudden onset of cold, painful leg

TARGET POPULATION

Patients with sudden onset of cold, painful leg

INTERVENTIONS AND PRACTICES CONSIDERED

1. Invasive (INV), aortography and bilateral lower extremity arteriography
2. Physiologic noninvasive tests including ankle-brachial index (ABI), transcutaneous oxygen pressure measurement, and exercise treadmill testing
3. Ultrasound (US)
    - Transthoracic echocardiography
    - Lower extremity with Doppler
    - Transesophageal echocardiography
4. Computed tomography angiography (CTA), lower extremity
5. Magnetic resonance angiography (MRA), lower extremity
6. Magnetic resonance imaging (MRI), heart function and morphology, with or without contrast
7. CT, heart function and morphology, with contrast

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in differential diagnosis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of peer-reviewed medical journals, and the major applicable articles were identified and collected.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the appropriateness criteria. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi technique to arrive at consensus. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the

participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by the Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible. If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

There has been extensive debate regarding the cost-benefit ratios when comparing digital subtraction angiography (DSA) and magnetic resonance angiography (MRA). At some institutions, DSA is done as an inpatient procedure and therefore may necessitate a 2-day hospital stay. If complications from this invasive approach occur, additional intervention and prolongation of the hospital stay may add cost as well as morbidity or even mortality. To be truly cost-effective, any noninvasive method would have to supplant, not just precede or supplement DSA.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Sudden Onset of Cold, Painful Leg

Radiologic Procedure	Rating	Comments	RRL*

Radiologic Procedure	Rating	Comments	RRL*
INV aortography and bilateral lower extremity arteriography	8		Low
CTA lower extremity	7	Distal abdominal aorta should be included.	Med
MRA lower extremity	7	Distal abdominal aorta should be included. See comments regarding contrast in the text below under "Anticipated Exceptions."	None
Physiologic noninvasive tests	6	Not required in the acute setting but may provide important physiologic information not obtained on imaging studies to further direct care.	None
US lower extremity with Doppler	5	Limitations include heavily calcified vessels and operator dependency. May be helpful for problem solving.	None
US echocardiography transthoracic	4	Generally not part of the initial workup. May be useful to look for source of emboli.	None
US echocardiography transesophageal	3	Generally not part of the initial workup. May be useful to look for source of emboli.	None
MRI heart function and morphology with or without contrast	3	Generally not part of the initial workup. May be useful to look for source of emboli.	None
CT heart function and morphology with contrast	2	Generally not part of the initial workup. May be useful to look for source of emboli.	High
Rating Scale: 1=Least appropriate, 9=Most appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Acute onset of a cold painful leg, although not directly a significant cause of mortality, contributes significantly to morbidity. The etiologies of acute onset of a

cold, painful leg are limited; the most common cause is arterial occlusion. Total venous outflow occlusion is another much less common cause. It often results in what is known clinically as "phlegmasia cerulea dolens" (precursor to venous gangrene) with lower extremity swelling, pain, and a dusky color. It is differentiated from arterial occlusion by the presence of distal arterial pulses. Other causes, such as prolonged exposure to cold and trauma, are rare and usually clinically obvious.

This condition generally requires urgent treatment, regardless of the etiology. Once the etiology is clinically defined, directing appropriate care of the patient requires assessing the source (i.e., embolic versus thrombotic occlusion) and extent of the underlying arterial obstruction. The available alternatives include noninvasive testing: duplex ultrasound (US), magnetic resonance angiography (MRA), computed tomography angiography (CTA), and catheter angiography.

Catheter Angiography

Digital subtraction angiography (DSA) remains the diagnostic gold standard for detecting peripheral vascular occlusive disease, but new and less invasive modalities are gradually replacing it. Obviously, one of the major benefits is the ability to diagnose and then treat disease with one procedure; a benefit which remains unmatched in vascular disease. There has been extensive debate regarding the cost-benefit ratios when comparing DSA and MRA. At some institutions, DSA is done as an inpatient procedure and therefore may necessitate a 2-day hospital stay. If complications from this invasive approach occur, additional intervention and prolongation of the hospital stay may add cost as well as morbidity or even mortality. To be truly cost-effective, any noninvasive method would have to supplant, not just precede or supplement DSA.

The incidence of complications with DSA varies greatly in published reports. Potential complications include those related to the use of contrast agents. Most worrisome are the rare fatal systemic reactions and contrast-induced nephropathy (CIN). The nephrotoxic effects are important to consider, as many patients who present with the sudden onset of a cold, painful leg are elderly, diabetic, and have impaired renal function. Also, many patients will have repeated angiography over the course of their disease, and minimizing the patient's radiation exposure should always be taken into consideration. Angiography has also always been criticized for its imperfect evaluation of outflow vessels, specifically for limited visualization of patent distal vessels beyond significant obstructive lesions.

Magnetic Resonance Angiography

One of the most heavily investigated alternatives is MRA. With improving speed of examinations as well as improving technology that reduces artifacts and venous contamination, it is proving to be a feasible, noninvasive alternative to catheter DSA. More recent research has demonstrated high sensitivity and specificity for detecting acute occlusive disease when compared to DSA. Much of the success comes as a result of 3D contrast-enhanced replacing 2D MRA, allowing for thinner slices and higher signal-to-noise ratios. MRA is an attractive alternative for diagnosing arterial disease, as it is noninvasive and has few associated complications. Its current speed and resolution have enabled MRA to become a

reliable method of quickly and accurately imaging the entirety of the lower vascular system.

Whereas, older techniques and sequences would require the patient to remain still for 30 minutes or more, contrast-enhanced scans can be completed much more quickly. Most of the information that interventionalists or vascular surgeons need can be gathered with MRA, including a general road map of arterial anatomy, including runoff vessels and collaterals, as well as the location and extent of significant stenoses and occlusions. Limitations include less accurate evaluation of smaller arteries and better results requiring more time-consuming technologies, including lower extremity coils. Also, limited information can currently be obtained on a routine basis regarding the character of vessel walls and flow dynamics, although time-resolved contrast-enhanced.

MRA techniques are beginning to provide qualitative flow information. Overestimation of stenosis in patients with vascular stents secondary to artifacts has been reported, as has routine overestimation. The latter appears to be dependent on the specific technique used and may or may not be a clinical problem in specific cases. This uncertainty highlights another barrier to the institution of MRA: the lack of a consensus on the best method for performing the study. In part, this is a function of the continuing evolution of technology, both software and hardware. Another concern with MRA is that most techniques have required the administration of a gadolinium-based contrast agent. With the realization of the risk of nephrogenic systemic fibrosis (NSF) in patients with underlying renal dysfunction who receive these contrast agents, there has been increased interest in using another imaging modality in such patients, in limiting the use of contrast in MRA, or in developing improved techniques of MRA that do not depend on the administration of contrast agents (see Anticipated Exceptions below).

Computed Tomography Angiography

As with MRA, there have been significant recent advances with CTA, with shorter imaging times and significantly better spatial resolution thanks to the advent of multidetector CT (MDCT). Where previously one contrast bolus was limited to imaging 40 cm of a given vascular territory, MDCT is capable of acquiring thin slices from the diaphragm to the ankles in less than 40 seconds using a single contrast bolus. Sophisticated postprocessing tools allow for 3D volumetric imaging for superior diagnostic accuracy and improved ease of interpretation. Postprocessing of massive amounts of raw data has proven vital to the success of CTA. Although it may be time-consuming, recent software platforms have made such efforts easier. The average postprocessing time varies, but this is a complicated task that requires the subtraction of bony structures, which are often at the center of the image, and takes an average of over 20 minutes.

The two most popular techniques for vessel analysis are volume rendering (VR) and maximum intensity projection (MIP), each with advantages and disadvantages. MIPs are very accurate for larger vessels (as distal as the infrapopliteal region) but less accurate for smaller vessels. Where MIP imaging cannot evaluate the vessel lumen, VR is good for evaluating embolic or vascular endothelial injury. It is also valuable in the evaluation of heavily calcified vessels.

It is not sufficient, however, for the sole evaluation of stenotic or occluded vessels.

CTA has proven accurate for evaluating arteries from the infrarenal to the infrapopliteal levels. To date, there have been no direct comparisons of CTA and MRA. CTA, however, has advantages over MRA due to its widespread availability and its usability in patients who have contraindications to MR, such as those who have defibrillators in place. CTA is also felt to be more accurate in depicting mural calcifications although heavy calcifications (over 50%) may also create artifact and overestimate the degree of stenosis. Discussions of cumulative radiation dosage have raised concerns, as MDCTA has been increasingly used for both preprocedure planning and postprocedure surveillance. Studies have emerged, however, that show lower radiation dosages for a single CTA examinations compared to DSA. Also, techniques tailored to the evaluation of lower limb vasculature have been published that allow reduced patient radiation by decreasing peak kilovoltage (kVp), with preserved ability to evaluate the smaller lower limb vessels.

Other Imaging Examinations

Duplex US is limited by the need for operator expertise, by poor accessibility of vessels, by heavy calcification, and often by poor overall accuracy if multilevel disease is present. Its advantages are that it can provide useful physiologic as well as anatomic information. Further, it is noninvasive, widely available, and relatively inexpensive.

Transthoracic echocardiography (TTE) or the more specific and more invasive transesophageal echocardiography (TEE) may be useful if it is thought that the onset of symptoms is related to embolization from the heart. The suspicion for this is particularly high in patients with known atrial fibrillation. It is not likely in the acute setting, however, that this knowledge will affect further evaluation or alter therapy for the acutely cold, painful leg. Similarly, cardiac MRI may be useful in defining the presence of cardiac thrombus or areas of cardiac dysfunction that might be the source of emboli, but this knowledge is not likely to have clinical impact in the acute setting.

Noninvasive Physiologic Testing

This includes measurement of ankle-brachial index (ABI), plethysmography, transcutaneous oxygen pressure measurement (TCPO2) and exercise treadmill testing. ABI measurement is simple and reliable and serves both as confirmation of arterial occlusion as the etiology of sudden onset of cold leg and as a baseline to guide further intervention. Useful physiologic information may also be obtained. In this clinical setting, other noninvasive tests generally are not helpful, as they do not provide specific information that will alter or guide therapy.

Summary

Minimally invasive methods of vascular imaging have grown in leaps and bounds over the past decade and will continue to evolve. DSA remains the gold standard for diagnosing peripheral vascular disease and continues to be the only modality that allows diagnosis and simultaneous treatment of pathology. This alone will

ensure that DSA continues to be a valuable tool. However, noninvasive imaging to evaluate the vasculature before an angiogram, or surgery, is becoming a more and more reasonable step. CTA and MRA have become accurate and attractive, less invasive modalities for initial evaluation. Peripheral vascular disease is a significant and growing problem, and continued research and development of current and emerging technologies will ultimately shape the standard of care.

Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF, also known as nephrogenic fibrosing dermopathy) was first identified in 1997 and has recently generated substantial concern among radiologists, referring doctors and lay people. Until the last few years, gadolinium-based MR contrast agents were widely believed to be almost universally well tolerated, extremely safe and non-nephrotoxic, even when used in patients with impaired renal function. All available experience suggests that these agents remain generally very safe, but recently some patients with renal failure who have been exposed to gadolinium contrast agents (the percentage is unclear) have developed NSF, a syndrome that can be fatal. Further studies are necessary to determine what the exact relationships are between gadolinium-containing contrast agents, their specific components and stoichiometry, patient renal function and NSF. Current theory links the development of NSF to the administration of relatively high doses (e.g., >0.2mM/kg) and to agents in which the gadolinium is least strongly chelated. The U.S. Food and Drug Administration (FDA) has recently issued a "black box" warning concerning these contrast agents (http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm142882.htm).

This warning recommends that, until further information is available, gadolinium contrast agents should not be administered to patients with either acute or significant chronic kidney disease (estimated glomerular filtration rate [GFR] <30 mL/min/1.73m^2), recent liver or kidney transplant or hepato-renal syndrome, unless a risk-benefit assessment suggests that the benefit of administration in the particular patient clearly outweighs the potential risk(s).

Abbreviations

- CT, computed tomography
- CTA, computed tomography angiography
- INV, invasive
- kVp, peak kilovoltage
- Med, medium
- MRA, magnetic resonance angiography
- MRI, magnetic resonance imaging
- US, ultrasound

Relative Radiation Level	Effective Dose Estimated Range
None	0
Minimal	<0.1 mSv

Relative Radiation Level	Effective Dose Estimated Range
Low	0.1-1 mSv
Medium	1-10 mSv
High	10-100 mSv

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Selection of appropriate radiologic imaging procedures to aid in differential diagnosis of patients with sudden onset of cold, painful leg

POTENTIAL HARMS

- Potential complications of digital subtraction angiography (DSA) include those related to the use of contrast agents. Most worrisome are the rare fatal systemic reactions and contrast-induced nephropathy (CIN).
- The nephrotoxic effects of DSA are important to consider, as many patients who present with the sudden onset of a cold, painful leg are elderly, diabetic, and have impaired renal function. Also, many patients will have repeated angiography over the course of their disease, and minimizing the patient's radiation exposure should always be taken into consideration.
- Some patients with renal failure who have been exposed to gadolinium contrast agents (the percentage is unclear) have developed nephrogenic systemic fibrosis (NSF), a syndrome that can be fatal. The U.S. Food and Drug Administration (FDA) has recently issued a "black box" warning concerning these contrast agents. This warning recommends that, until further information is available, gadolinium contrast agents should not be administered to patients with either acute or significant chronic kidney disease (estimated glomerular filtration rate [GFR] <30 mL/min/1.73m^2), recent liver or kidney transplant or hepato-renal syndrome, unless a risk-benefit assessment suggests that the benefit of administration in the particular patient clearly outweighs the potential risk(s).

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Additional information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR) Appropriateness Criteria® Radiation Dose Assessment Introduction document (see "Availability of Companion Documents" field).

CONTRAINDICATIONS

CONTRAINDICATIONS

Magnetic resonance imaging (MRI) is contraindicated in patients with defibrillators in place.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Mettmann MA, Brozzetti KA, Yucel EK, Holtzman SR, Baum RA, Foley WD, Ho VB, Mammen L, Narra VR, Rybicki FJ, Stein B, Moneta GL, Expert Panel on Vascular Imaging. ACR Appropriateness Criteria® sudden onset of cold, painful leg. [online publication]. Reston (VA): American College of Radiology (ACR); 2008. 5 p. [24 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1998 (revised 2008)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Vascular Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Michael A. Bettmann, MD; Kelly A. Brozzetti, MD; E. Kent Yucel, MD; Stephen R. Holtzman, MD; Richard A. Baum, MD; W. Dennis Foley, MD;

Vincent B. Ho, MD, MBA; Leena Mammen, MD; Vamsidhar R. Narra, MD; Frank J. Rybicki, MD, PhD; Barry Stein, MD; Gregory L. Moneta, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

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The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

ACR Appropriateness Criteria® *Anytime*, *Anywhere*™ (PDA application). Available from the ACR Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.
- ACR Appropriateness Criteria® radiation dose assessment introduction. American College of Radiology. 2 p. Electronic copies: Available from the American College of Radiology Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 20, 2001. The information was verified by the guideline developer on March 14, 2001. This NGC summary was updated by ECRI Institute on August 10, 2009.

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